Section 5 – 510(k) Summary

K080905

JUL 16 2008

General Information

Owner's Name:	Quantum Medical Imaging, LLC
Address:	2002-B Orville Drive North Ronkonkoma, NY 11779-7661
Telephone Number:	(631) 567-5800
Fax Number:	(631) 567-5074
Contact Person:	Mark Camirand; Director Q.A./Compliance
Subject Device Name:	Quantum / Canon CXDI Integration System
Common/Usual Name:	Stationary Electrostatic X-Ray System
Product Codes:	LLZ; KPR; MQB
Regulation:	21 CFR 892.2050 / 21 CFR 892.1680 / 21 CFR 892.1650
Classification:	Class II
Predicate Device Names:	Quantum Q-Rad Radiographic System / Quantum DiRex System / Canon CXDI-40EG Digital Radiography System / Canon CXDI-50G Digital Radiography System
Manufacturers:	Quantum Medical Imaging, LLC / Canon, Inc.
Premarket Notifications:	K011486 / K072010 / K050987 / K031447

Device Description
The Quantum / Canon CXDI Integration System consists of add-on software that will allow the use of the currently marketed Quantum Q-Rad Radiographic System with the currently marketed Canon CXDI Series System, including models CXDI-40EG or CXDI-50G, as a fully integrated digital imaging system.

Intended Use
The Quantum / Canon CXDI Integration System provides diagnostic quality images to aid the physician with diagnosis. The System can be used to perform radiographic exposures of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts. The System is not indicated for use in mammography.

Performance Testing
Performance data demonstrated that the Quantum / Canon CXDI Integration System is substantially equivalent to the predicate devices and/or met pre-determined acceptance criteria. The risks associated with use of the new device were found acceptable when evaluated by standardized risk/hazard analysis techniques. Performance testing was successfully completed on the system in accordance with predetermined protocols based on the system design inputs.

No biocompatibility testing was conducted in support of this 510(k); all patient-contacting materials used in the manufacture of the Quantum / Canon CXDI Integration System have been previously cleared for similar devices.

Conclusion
The Quantum / Canon CXDI Integration System meets all the pre-determined acceptance criteria of the testing performed to confirm safety and effectiveness; the System is substantially equivalent to the predicate devices.

Section 4 – Indications for Use Statement

510(k) Number (if known): K080905

Device Name: Quantum / Canon CXDI Integration System

Indications for Use:

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Prescription Use __X___ (Per 21 CFR 801 Subpart D)

OR

Over-the -Counter Use ____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080905

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2008

Ms. Pamela Papineau, RAC
Consultent
Quantum Medical Imaging, LLC
2002-B Orville Drive North
RONKONKOMA NY 11779-7661

Re: K080905
Trade/Device Name: Quantum / Canon CXDI Integration System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 3, 2008
Received: June 4, 2008

Dear Mr. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4 – Indications for Use Statement

510(k) Number (if known): _____

Device Name: Quantum / Canon CXDI Integration System

Indications for Use:

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Prescription Use __X___ OR Over-the -Counter Use ____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

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